K091458

## 510(k) Summary

OCT 15 2009

# HyperForm™ Occlusion Balloon Catheter
# HyperGlide™ Occlusion Balloon Catheter

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| **510(k) Summary** | This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R § 807.92. |
| **Applicant** | Micro Therapeutics, Inc. dba ev3 Neurovascular |
| **Submitter** | Micro Therapeutics, Inc.<br>9775 Toledo Way<br>Irvine, CA 92618<br>Tel: 949-680-1237<br>Fax: 949-465-1737 |
| **Contact Person** | Tom Daughters<br>Director, Regulatory Affairs |
| **Date Prepared** | May 8, 2009 |
| **Device Trade Name** | HyperForm™ Occlusion Balloon Catheter<br>HyperGlide™ Occlusion Balloon Catheter |
| **Device Common Name** | Occlusion Balloon Catheter |
| **Classification Name** | Catheter, Intravascular Occluding, Temporary (21 CFR 870.4450, Product Code MJN |
| **Classification Panel** | Cardiovascular |
| **Predicate Devices** | Equinox Occlusion Balloon Catheter (K001237), HyperForm Occlusion Balloon Catheter (K011656), and HyperGlide Occlusion Balloon Catheter (K011526, K090728). |
| **Intended use** | The MTI HyperForm™ Occlusion Balloon Catheters are indicated for use in blood vessels of the peripheral and neuro vasculature where temporary occlusion is desired. These catheters offer (1) a vessel selective technique of temporary vascular occlusion, which is useful in selectively stopping or controlling blood flow, and (2) for balloon-assisted embolization of intracranial aneurysms.<br><br>The MTI HyperGlide™ Occlusion Balloon Catheters are indicated for use in blood vessels of the peripheral and neuro vasculature where temporary occlusion is desired. These catheters offer (1) a vessel selective technique of temporary vascular occlusion, which is useful in selectively stopping or controlling blood flow, and (2) for balloon-assisted embolization of intracranial aneurysms. |
| **Device Description** | The HyperForm™ Occlusion Balloon Catheter is a single lumen tapered catheter with a non-detachable low inflation pressure compliant balloon attached to the distal end of the catheter. The catheter is designed to track over a 0.010" guidewire, and requires insertion of the guidewire to occlude the catheter shaft lumen to allow inflation of the balloon. Two platinum markers provide angiographic |

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| | visualization of the balloon length and facilitate intravascular placement of the balloon prior to inflation. The catheter shaft is hydrophilically coated to assist in catheter advancement within the vasculature. The HyperForm catheter is supplied sterile for single use as a system, which includes the required 0.010" guidewire. This description has not changed from the predicate device (K011656).<br><br>The HyperGlide™ Occlusion Balloon Catheter is a single lumen balloon catheter with a maximum outer diameter of 2.8F tapering to 202F at the distal tip. The distal end of the catheter has a non-detachable low inflation pressure compliant balloon. Two platinum markers provide angiographic visualization of the balloon length and facilitate intravascular placement of the balloon prior to inflation. The catheter shaft is hydrophilically coated to assist catheter placement within the vasculature. The catheter is supplied sterile for single use as a system, which includes the required 0.010" guidewire. This description has not changed from the predicate device (K011526, K090728). |
| **Performance data** | No bench testing and biocompatibility testing was performed to support a determination of substantial equivalence. Results from submitters experience and literature review provides assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. |
| **Summary of Substantial Equivalence** | The proposed HyperForm™ and HyperGlide™ Occlusion Balloon Catheters are identical to the predicate devices and use the same basic technology as the predicate devices. The proposed devices share the following similarities to the predicate devices:<br>• Same intended use (all predicates)<br>• Same balloon technology and specifications (all predicates)<br>• Same catheter technology and characteristics (all predicates)<br>• Same other product technology and specifications (all predicates) |
| **Conclusion** | Based on the similar indications for use, technological characteristics and performance testing, ev3 believes the HyperForm™ and HyperGlide™ Occlusion Balloon Catheters are substantially equivalent to the Equinox Occlusion Balloon Catheter (K001237), the HyperForm™ Occlusion Balloon Catheter (K011656), and the HyperGlide™ Occlusion Balloon Catheter (K011526, K090728). |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room W-O66-0609
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ev3 Neurovascular
ATTN: Tom Daughters
Director, Regulatory Affairs
9775 Toledo Way
Irvine, CA 92618

OCT 1 5 2009

Re: K091458
Trade/Device Name: Hyperform & Hyperglide Occlusion Balloon Catheters
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: MJN
Dated: September 18, 2009
Received: September 21, 2009

Dear Mr. Daughters:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Indications for Use Statement**

510(k) Number (if known): K091458

Device Name: HyperForm™ Occlusion Balloon Catheters

HyperGlide™ Occlusion Balloon Catheters

Indications for Use:

The MTI HyperForm™ Occlusion Balloon Catheters are indicated for use in blood vessels of the peripheral and neuro vasculature where temporary occlusion is desired. These catheters offer (1) a vessel selective technique of temporary vascular occlusion, which is useful in selectively stopping or controlling blood flow, and (2) for balloon-assisted embolization of intracranial aneurysms.

The MTI HyperGlide™ Occlusion Balloon Catheters are indicated for use in blood vessels of the peripheral and neuro vasculature where temporary occlusion is desired. These catheters offer (1) a vessel selective technique of temporary vascular occlusion, which is useful in selectively stopping or controlling blood flow, and (2) for balloon-assisted embolization of intracranial aneurysms.

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| Prescription Use X<br>(Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____<br>(21 CFR 801 Subpart C) |

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vanderslice

ivision Sign-Off)
ivision of Cardiovascular Devices

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